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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,371	04/06/2001	David Hung	05284.00085	3897

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/827,371	Hung
Examiner	**Art Unit**
Michele Flood	1651

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 9, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above, claim(s) *12-15* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6 and 8-11* is/are rejected.

7) ☒ Claim(s) *7* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group I, Claims 1-11, in Paper No. 6 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase "administering an agent to the patient that increases retrievable fluid from a breast duct" because the phrase is awkward and confusing. As drafted, the recitation of the phrase makes it appear that the patient increases retrievable fluid from a breast duct, instead of an agent which is administered to the patient. Applicant may overcome the rejection by replacing the phrase with administering to the patient an agent that increases retrievable fluid from a breast duct.

With regard to Claim 3, line 6, there appears an apparent misspelling. Applicant may overcome the rejection by replacing "biocompatable" with biocompatible.

The term "a small organic molecule" in claim 4 is a relative term which renders the claim indefinite. The term "a small organic molecule" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, it is uncertain as to how small an organic molecule has to be to be considered " a small organic molecule" by Applicant. Is the subject matter to which Applicant intends to direct the invention an organic molecule having a molecular weight of 200, 500, 75,000, 100,000 or 500,000 Daltons?

Regarding claim 5, the parenthetical phrase "for example", i.e., "(*e.g.* dextran 70)", renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 7 is rendered indefinite by the phrase "wherein the agent is intraductally administered agent" because the phrase makes the claim grammatically incorrect. Applicant may overcome the rejection by deleting the word, "agent", which appears after "administered".

Claims 8 and recite the limitation "the increased breast fluid" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "retrievable fluid" in 2. The claim lacks clear antecedent basis for this limitation.

Claim 11 recites the limitation "the step of analyzing" in 1. The claim lacks clear antecedent basis for this limitation.

All other claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunn et al. (U) or Nguyen (D).

Applicant claims a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering an agent to the patient that increases retrievable fluid from a breast duct. A dependent claim is directed to a method

wherein administering is accomplished by a mode selected from the group consisting of administering the agent intraductally, systemically, and topically.

With regard to the systemic administration of an agent that increases retrievable fluid from a breast duct of a patient, Gunn teaches a method of preparing for intraductal retrieval of fluid, cells and/or material from a breast duct comprising the administration of an agent which increases retrievable fluid from a breast duct. For instance, Gunn teaches administering a recombinant human growth hormone to mothers of preterm infants and having insufficient milk production to increase breast milk volumes.

Nguyen teaches a method for preparing intraductal retrievable fluid, cells and/or materials comprising the administration to a patient a polysaccharide extract obtained from plants, which increases the secretion of milk in women. The polysaccharide product taught by Nguyen is administered orally or by injection.

Therefore, each of the cited references is deemed to anticipate the claimed subject matter.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchens (V).

Hutchens teaches a method for preparing for intraductal retrieval of fluid, cells and/or material from a breast duct comprising the topical administration of an agent which increases retrievable fluid from a breast duct. For instance, on page 50 under "Externally", Hutches teaches that leaves of castor bean (*Ricinus communis*) are galactogopic when applied to the breast: "Canary Island women have used the leaves to increase their secretion of milk for

centuries." On page 52, lines 26-29, Hutchens teaches applying a poultice of castor bean leaves over the breast of nursing women as a lactagogue.

The reference anticipates the claimed subject matter.

Claims 1, 2, 4, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin (C).

Applicant further claims a method further comprising collecting a portion of the increased breast duct fluid from a breast duct; and, further comprising analyzing one or more of cells, fluid or other material in the breast duct after the retrievable fluid has increased and a portion of it has been collected.

Horrobin teaches the oral, parenteral or other internal administration and topical administration of gamma linolenic acid, dihomo-gamma-linolenic acid in the form of evening primrose oil to mothers to stimulate the production of milk flow. Milk samples were collected from the patients and analyzed after the increased milk flow. See Column 2, lines 10-67 bridging Column 3, lines 1-3, and lines 24-34; Column 4, lines 16-24; and, Column 5, lines 9-66 to Column 6, lines 1-12. The pharmaceutical compositions disclosed by Horrobin are incorporated into various dietary supplements, such as margarine or other foodstuff and feed.

The reference anticipates the claimed subject matter.

Claims 1-3, 5 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Love (A) or Barsky et al. (E).

Applicant further claims a method wherein the step of analyzing comprises identifying a marker of a breast condition.

Love teaches a method for preparing for intraductal retrievable of fluid of fluid, cells and/or other material from a breast duct of a patient comprising the intraductal administration of a washing to a milk duct in the breasts of female human patients to retrieve fluids, marker substances, and cellular materials (see abstract). In Column 5, lines 61-64, Love teaches physiologic saline as a preferred washing fluid, "but contrast media and other physiologically sterile fluids may also be used." In Column 6, lines 55-67, Love discloses that "The volume of fluid introduced into the ductal network D_2 will be sufficiently large so that substantially the entire volume of the ductal network may be filled with the washing fluid and excess fluid will flow from the network as it is displaced by additional fluid input . . . The remaining fluid will continue to be introduced and will thus flush the cellular and other marker materials from the ductal network into the opening . . ." After collection of the washing fluid comprising the retrievable fluid obtained from the breast duct through a double lumen catheter, Love teaches analyzing the fluid to identify a marker of a breast condition (see Column 5, lines 38-44).

Barsky teaches a method of washing the nipple of a patient's breast with a keratinolytic agent, such as 5% to 50% acetic acid, to remove keratin plugs which normally occlude the duct orifice and which normally inhibit the binding of labeling reagent to a tissue marker; and, then

exposing the treated nipple with a labeling reagent which binds to a tissue marker. Barsky further teaches a step of dilating the breast duct with saline and removing cells through a cannula as washings, and identifying the collected cells by histopathological analysis (see Column 6, lines 6-65). Barksy does not expressly teach the process for the administration of the dekeratinizing agent as a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering to a patient an agent which increases retrievable fluid from a breast duct, however, the claimed method is inherent to the method taught by Barsky because Barsky teaches that applying the dekeratinizing agent to the nipple removes keratin-containing materials which normally occlude the duct orifice, which allows for successful labeling of the ductal orifices and permits for cannulation with washings, and the subsequent collection of the washings thereof; and, hence increase retrievable fluid from a breast duct.

Therefore, each of the cited references is deemed to anticipate the claimed subject matter.

Claims 1, 2, 4 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Quay et al. (B).

Quay teaches a method for preparing for intraductal retrievable of fluid, cells and/or other material from a breast duct of a patient comprising the intranasal, intramuscular or intravenous administration of a peptide hormone, oxytocin, to a patient (see Column 6, lines 6-67 to Column 7, lines 1-30). In Column 7, lines 31-57, Quay teaches that the administration of effective

amounts of oxytocin stimulates the expression of mammary fluid in non-lactating females with the aid of negative pressure to the nipple by a breast pump after a first administration of an oxytocin spray. A biological sample is collected from the expressed mammary fluid, during or after the mammary fluid expression step. After the sample is collected, a bioassay is conducted on the sample to determine the presence and/or amount of a selected breast marker.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogata et al. (F).

Applicant further claims a method as in claim 2, wherein the agent is intraductally administered and the agent is in a state selected from the group consisting of a non-liquid, a gel, an emulsion, a gas and a semi-solid.

Ogata teaches a method of injecting pressurized ozone into the teat orifice of a cow's (i.e, a patient's) breast via an ozone generator. In Column 3, lines 52-64, Ogata teaches that injecting pressurized ozone into the breast significantly expands the extremely narrow and elongated milk

vessels located at deep regions, which thereby promotes discharge [of fluid] to the outside of the body.

The teachings of Ogata are set forth above. Although Ogata does teach administering ozone through the teat orifice of a cow (i.e., a patient) into the interior of the breast (see Column 1, lines 66-67 to Column 2, lines 1-4), Ogata does not expressly teach a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering to the patient an agent that increases retrievable fluid from a breast duct, wherein the duct is intraductally administered. Although the "teat orifice"may not expressly constitute a breast duct *per se*, it would have been obvious to one of ordinary skill in the art at the time the invention was made to intraductally administer to the breast of a patient (i.e., a cow) the ozone taught by Ogata because Ogata teaches that ozone expands the milk vessels (also known as milk ducts) located at deep regions within the breast and promotes discharge. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to intraductally administer the ozone taught by Ogata to the breast of a patient (i.e., a cow) in a method of preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient because Ogata teaches that ozone kills disease-causing microbes, supplies oxygen to the breast tissue, is cost-effective, and can be applied to a treatment for a dried up or blinded teat (see Column 3, lines 52 to Column 4, lines 1-58; and, Column 7, lines 7-11).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Allowable Subject Matter

Claim 7 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

Michele C. Flood.

MCF

July 9, 2002